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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/683,399	12/21/2001	Brian J. Martinell	38-21(51470)	2956
46795 7590 02/27/2007 FULBRIGHT & JAWORSKI, LLP 600 CONGRESS AVENUE, SUITE 2400 AUSTIN, TX 78745			EXAMINER HELMER, GEORGIA L	
			ART UNIT	PAPER NUMBER
			1638	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/27/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/683,399	<b>Applicant(s)</b> MARTINELL ET AL.	
	<b>Examiner</b> Georgia Helmer	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Status of the Claims***

1. The Office acknowledges receipt of Applicant's Amendment 6 November 2006.
2. Claims 1 and 16 have been amended. Claims 1-19 are pending, and are examined in the instant action.
3. All rejections not addressed below have been withdrawn.
4. This action is made FINAL.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 103***

6. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martinelli, et al, US 6, 384,301, and Trolinder et al, US 5,994,624, in view of Jefferson et al, 1987, for reasons of record as set forth in the Office Action mailed 5 April 2006, as well as those set forth below.

Applicant claims a method of early identification of germline transformed plants comprising steps of: (a) transforming meristematic or cotyledonary tissue with a plant expressible construct comprising at least one nucleic acid sequence encoding a protein to obtain transformed plant tissue; (b) producing a shoot from the transformed plant tissue; (c) growing roots from the shoot; (d) obtaining a piece of root tissue or extract thereof from the transformed plant tissue; assaying the root tissue or extract thereof for the presence of the nucleic acid sequence and (e) identifying roots that assay positive for said at least one nucleic acid sequence as putative germline transgenic plants. Dependent claims are drawn the method wherein the plant expressible construct

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encodes a protein conferring a trait to the plant, the plant expressible construct comprises at least two nucleic acid sequences, wherein the roots are grown in the presence of a selection agent; wherein the selection agent is kanamycin; wherein the selection agent is glyphosate; wherein the transformation is via Agrobacterium mediated transformation or particle mediated transformation; wherein the plant is a dicot plant; a soybean plant, or a cotton plant.

US 6,384,301 teaches a method of identification of germline transformed soybean (claims 13 and 14) cells and plants comprising steps of: (a) transforming meristematic tissue (column 7, lines 24-25) with a plant expressible construct comprising at least one nucleic acid sequence encoding a protein (column 7, lines 30) to obtain transformed plant tissue; (b) producing a shoot (column 7, lines 43-49) from the transformed plant tissue; (c) growing roots from the shoot (column 7, lines 43-49); ((e) identifying roots that assay positive for said at least one nucleic acid sequence as putative germline transgenic plants (column 4, lines 60-63 and column 9, lines 32-43).

Soybean is a dicot plant (claim 13 and 14). Glyphosate is an herbicide (claim 2).

Claim 1 (d) has been amended to recite "obtaining a piece of root tissue or extract thereof from the transformed plant tissue, assaying the root tissue or extract thereof for the presence of the nucleic acid sequence".

The term "piece" is interpreted broadly to include pieces of indeterminate or variable size, from very large to very small, of root tissue. Accordingly, the language of the '301 reference, column 9, lines 32-43, says:

"Of the seven target of 12 embryos for the treatment group, three phenotypic shoots were observed, one of these rooted and was sent to the greenhouse. It tested positive for GUS tissue in the vascular tissue, which indicates germline transformation..." is interpreted to say that a piece of the root was rooted and tested positive for GUS. The GUS assay is used to demonstrate the expression of the *uidA* reporter gene.

Martinelli et al ('301) do not teach obtaining a piece of root tissue or extract thereof from the transformed plant tissue, assaying the extract thereof for the presence of the nucleic acid.

Jefferson, et. al, 1987, teach obtaining a piece of tobacco root tissue, making an extract thereof from the transformed plant tissue and assaying the root tissue or extract thereof for the presence of the nucleic acid. See (Figure 2, and legend, p. 3903; Table I, p. 3903). Figure 2, titled "beta glucuronidase activity in extract of different organs of transformed and non-transformed tobacco plant, gives data for the transformed root. Table I titled GUS specific activity, shows data for root, final item in table, and indicates that these data are from plant tissue extracts. See Table 1, legend, 1<sup>st</sup> sentence. All Jefferson's data obtained using the fluorometric assay are performed using extracts of tissue; this includes Figure 2 data and Table I data.

It would have been obvious to one of skill in the art, at the time of the invention was made, to use the GUS analysis system of Jefferson, et. al, whereby an extract is made from plant root tissue, as "expression of GUS can be measured accurately using

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fluorometric assays of very small amounts of transformed plant tissue" and has been shown to function well in the confirmation of the expression of specific nucleic acid sequences in transgenic plant tissue. See Jefferson, Abstract, p. 3901.

One skilled in the art would have been motivated to so, with a reasonable expectation of success, especially in the absence of evidence to the contrary.

Accordingly, the claimed invention is prima facie obvious in view of the prior art.

### ***Double Patenting***

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-9 and 13-14 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 and 13 of U.S. Patent No. 6,384,301. Although the conflicting claims are not identical, they are

not patentably distinct from each other because the species claims of patent 6,384,301 renders the genus claims of the instant application obvious.

This is a provisional obviousness-type double patenting rejection since no claims have been allowed in the instant case.

### Remarks

9. Claims 1-19 are not allowed in view of the prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

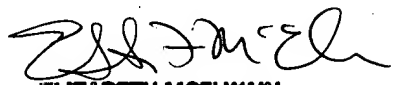
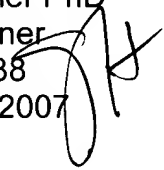
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia Helmer whose telephone number is 571-272-0796. The examiner can normally be reached on 10-6 Monday through Thursday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia Helmer PhD  
Patent Examiner  
Art Group 1638  
February 19, 2007



ELIZABETH MCELWAIN  
PRIMARY EXAMINER